

UConn Health
Office of Clinical & Translational Research
Standard Operating Procedures

Title: Contract Amendments	
Relates to Policy/Procedure:	
SOP#: 305-12	Version 2.0
Prepared by: J. Kulko, MS, MSN	Original date: June 28, 2012
Approved by: J. Kulko, MS, MSN	Date approved: August 19, 2016

Purpose and Applicability: The purpose of this document is to establish a uniform process for the review, negotiation, and approval of Contract Amendments for clinical trials open at UConn Health.

Background and Significance: No SOPs exist at UConn Health that describe the processes that govern the negotiation and approval of all contract Amendments for open Clinical Trials at UConn Health.

Scope: This SOP describes the necessary steps for the approval of an amendment to a contract for an open clinical trial at UConn Health.

Responsibilities:

Contract Specialist:

- a. Receives the amendment from sponsor or research staff
- b. Reviews proposed amendment
- c. Identifies type of Amendment
 - a. Contract
 - b. Budget
- d. Contract - Resends changes to Sponsor with if necessary, redlines amendment incorporating input from PI if required

Administrative and Clinical Research Coordinator:

- a) Reviews the amendment if it involves the budget
- b) Obtains PI approval of budget change
- c) Signs off on the amendment in an email to Contract Specialist

Fiscal Assistant:

Gives the Amendment a log number and logs it in to Access database with date received
Gets signatures of PI and Designated Institutional Signatory* on approved amendment

- a) Emails Sponsor for signature and records the date it is sent out
- b) Records date received back from Sponsor
- c) Keeps electronic copy in folder on OCTR I drive

Reimbursement Analyst:

- a) Subsidizes the clinical trial budget accounting

Procedural Steps: These procedural steps are done by the appropriate OCTR staff and include the following:

- a) Contracts Specialist receives clinical trial amendment
- b) Copy sent to Fiscal Assistant so it can be given a log number and logged in to Access data base with date received
- c) Amendment is reviewed by Contracts Specialist

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- d) Contracts Specialist makes appropriate changes to document with PI input if necessary
- e) Administrative & Clinical Research Coordinator reviews the amendment, if it involves budget
- f) Sign off on budget from the PI and Administrative & Clinical Research Coordinator via e-mail to Contracts Specialist
- g) Final document sent for signature by PI and Designated Institutional Signatory*
- h) Kept in the electronic file on OCTR I drive
- i) Electronic file emailed to Sponsor for signature
- j) Date noted in Access database when sent to Sponsor
- k) Date noted in Access when signed amendment returned from Sponsor
- l) Copy sent to PI
- m) Copy kept in electronic file on OCTR I drive
- n) Reimbursement Analyst subsidizes the clinical trial budget if necessary

Revision date: 8/19/16; 1/6/16	Revised by: D. Clavette
Reason for revision: 2.0 Reflect changes in system; name change 1.0 Update distribution of final executed amendment	
Date revised version sent to archives & current revision version # advanced: 8/19/16	

*See List of Institutional Signatories